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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/396,539	09/14/1999	PETER PALESE	7682-048	7591

7590 06/16/2004

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EXAMINER	
MCKELVEY, TERRY ALAN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.42

Office Action Summary	Application No.	Applicant(s)	
	09/396,539	PALESE ET AL.	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/19/01; 1/7/03*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *35,36,38-40,42,43,46-51 and 54-61* is/are allowed.

6)☐ Claim(s) *37, 41, 44, and 52-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/01; 6/01; 6/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All objections and rejections not repeated in the instant Action have been withdrawn due to applicant's response to the previous Action.

Election/Restrictions

Because the claims are free of the prior art, the previous election of species requirement has been withdrawn and claims 35-61 are under examination. In view of the above noted withdrawal of the restriction requirement, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 112

Claims 52-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a new rejection necessitated by the applicant's amendment adding claims 52-53 filed 1/7/03.

The use of "plasmid DNA contains a heterologous nucleotide sequence" in claim 52 renders the claims vague and indefinite because the metes and bounds of what constitutes "heterologous" in this context is unclear. Is heterologous in reference to the (parent) plasmid DNA? Or, is heterologous in reference to the DNA in the plasmid expressing an influenza RNA that is heterologous with respect to the other influenza RNAs being expressed? In other words, is the virus of claim 53 necessarily a chimeric virus, or does the claim 53 virus read on non-chimeric virus, in which case an art rejection is appropriate. It appears that the applicant intended that the latter interpretation of heterologous was intended and thus claim 53 would necessarily be limited to chimeric virus being produced. Amending the claims to more clearly define the context of "heterologous" and whether the virus produced is chimeric would be remedial.

Double Patenting

Claims 37, 41, 44, and 53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-26 of U.S. Patent No. 5,166,057, for reasons of record set forth in the paper mailed 12/19/00 (and extended to new claim 53 as necessitated by the applicant's amendment filed 6/19/01). Applicants' arguments filed 6/19/01 have been fully considered but they are not deemed to be persuasive.

Claims 37, 41, 44, and 53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-25 of U.S. Patent No. 5,854,037, for reasons of record set forth in the paper mailed 12/19/00 (and extended to new claim 53 as necessitated by the applicant's amendment filed 6/19/01). Applicants' arguments filed 6/19/01 have been fully considered but they are not deemed to be persuasive.

Claims 37, 41, 44, and 53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,001,634, for

reasons of record set forth in the paper mailed 12/19/00 (and extended to new claim 53 as necessitated by the applicant's amendment filed 6/19/01). Applicants' arguments filed 6/19/01 have been fully considered but they are not deemed to be persuasive.

Response to Arguments

The applicant argues that the test for obvious variation is whether the subject matter of the claim in the subsequent patent or application would have been obvious to a person of ordinary skill in the art in view of the prior art and the subject matter of the claim of the prior patent, and the Examiner has not established why a person of ordinary skill in the art would conclude that the invention defined by pending claims 37, 41, and 44 are an obvious variation of the issued claims of the (three patents). It is argued that there is nothing in the prior art that would suggest any method for creating recombinant negative strand RNA viruses and in particular, the methods claimed in the instant application. These arguments are not persuasive for the following reasons.

First, the rejected claims are all directed to chimeric virus made by the claimed methods, not the methods themselves. The cited patents all claim chimeric viruses made by a

different, but related method, which viruses all are totally encompassed by the broader scope of the instantly claimed chimeric viruses.

Second, claims 37, 41, 44, and new claim 53 are generic to all that is recited in the cited claims of the three cited patents. That is, claims 16-26 of U.S. Patent No. 5,166,057, claims 13-25 of U.S. Patent No. 5,854,037, and claims 1-6 of U.S. Patent No. 6,001,634 fall entirely within the scope of claims 37, 41, 44, and 53 or, in other words, claims 37, 41, 44, and 53 are anticipated by claims 16-26 of U.S. Patent No. 5,166,057, claims 13-25 of U.S. Patent No. 5,854,037, and claims 1-6 of U.S. Patent No. 6,001,634. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is **either** anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). In the instant case, claims 37, 41, 44, and 53 are anticipated by the cited claims of the cited patents.

Third, as indicated in the previous Office Action, the nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. Because claims 37, 41, 44, and 53 are anticipated by the cited claims of the cited patents, the instant claims, if allowed, would extend the patent protection of the inventions of the cited claims of the cited patents in addition to providing patent protection to the chimeric viruses not encompassed by the claims of the cited patents. Also, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the patent(s), then two or more different assignees would hold a patent to the claimed chimeric viruses of the cited claims of the cited patents (because those claims would also be encompassed by the instant claims if issued in a patent), and thus improperly there would be possible harassment by multiple assignees for the same claimed invention. These arguments which are based upon the rationale for nonstatutory double patenting clearly stated in the basis for double patenting in the previous Office Action, were not specifically addressed by the applicant and thus the

applicant's arguments concerning double patenting are not persuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

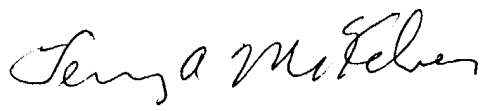
Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such

papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

June 14, 2004